Application No. 10/671,710 Docket No.: N9810.0030/P030 Reply to Office Action of December 31, 2007

## **AMENDMENTS TO THE CLAIMS**

- 1. (Currently amended) A method of administering sumatriptan or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition to provide transmucosal absorption of a pharmacologically effective amount of sumatriptan through the oral mucosa of the mammal to the systemic circulatory system of the mammal, the spray comprising: sumatriptan or a pharmaceutically acceptable salt thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and a polar solvent in an amount between 30 and 99.69 percent by weight of the total composition, wherein a therapeutically pharmacologically effective amount of sumatriptan is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system.
- 2. (Previously Presented) The method of claim 1, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.
- 3. (Previously Presented) The method of claim 2, wherein the polar solvent is present in an amount between 37 and 98.58 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.
- 4. (Previously Presented) The method of claim 3, wherein the polar solvent is present in an amount between 60.9 and 97.06 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.
- 5. (Previously Presented) The method of claim 1, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C<sub>2</sub> to C<sub>8</sub> mono- and poly-alcohols, and C<sub>7</sub> to C<sub>18</sub> alcohols of linear or branched configuration.

- 6. (Previously Presented) The method of claim 1, wherein the polar solvent comprises polyethylene glycol.
- 7. (Previously Presented) The method of claim 1, wherein the polar solvent comprises ethanol.
- 8. (Previously Presented) The method of claim 2, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.
  - 9. (Previously Presented) The method of claim 1, comprising sumatriptan succinate.
  - 10. (Canceled).
- 11. (Previously Presented) The method of claim 1, wherein the amount of the spray is predetermined.

## Claims 12-23 (Canceled).

- 24. (Currently amended) A method of administering sumatriptan or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition to provide transmucosal absorption of a pharmacologically effective amount of sumatriptan through the oral mucosa of the mammal to the systemic circulatory system of the mammal, the spray comprising: sumatriptan or a pharmaceutically acceptable salt thereof in an amount between 0.005 and 55 percent by weight of the total composition; and a non-polar solvent in an amount between 30 and 99.69 percent by weight of the total composition, wherein a therapeutically pharmacologically effective amount of sumatriptan is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system.
- 25. (Previously Presented) The method of claim 24, further comprising a taste mask and/or flavoring agent in an amount between 0.1 and 10 percent by weight of the total composition.

oil, fruit flavors, sweeteners, and mixtures thereof.

- 27. (Previously Presented) The method of claim 24, wherein the solvent is selected from the group consisting of  $(C_2-C_{24})$  fatty acid  $(C_2-C_6)$  esters,  $C_7-C_{18}$  hydrocarbons of linear or branched configuration,  $C_2-C_6$  alkanoyl esters, and triglycerides of  $C_2-C_6$  carboxylic acids.
- 28. (Previously Presented) The method of claim 27, wherein the solvent is a triglyceride.
  - 29. (Previously Presented) The method of claim 24, comprising sumatriptan succinate.
  - 30. (Canceled).
- 31. (Previously Presented) The method of claim 24, wherein the amount of the spray is predetermined.

Claims 32-43 (Canceled).

44. (Currently amended) A method of administering sumatriptan or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with a buccal spray composition to provide transmucosal absorption of a pharmacologically effective amount of sumatriptan through the oral mucosa of the mammal to the systemic circulatory system of the mammal, the spray comprising: sumatriptan or a pharmaceutically acceptable salt thereof in an amount between 0.2 and 10 percent by weight of the total composition; and a polar solvent comprising propylene glycol and ethanol in an amount between 50 and 99.69 percent by weight of the total composition, wherein a therapeutically pharmacologically effective amount of sumatriptan is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system.

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- 46. (Previously Presented) The method of claim 45, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.
- 47. (Previously Presented) The method of claim 46, wherein the polar solvent is present in an amount between 37 and 98.58 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.
- 48. (Previously Presented) The method of claim 47, wherein the polar solvent is present in an amount between 60.9 and 97.06 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.
- 49. (Previously Presented) The method of claim 45, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400

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and 1000,  $C_2$  to  $C_8$  mono- and poly-alcohols, and  $C_7$  to  $C_{18}$  alcohols of linear or branched configuration and the non-polar solvent is selected from the group consisting of  $(C_2-C_{24})$  fatty acid  $(C_2-C_6)$  esters,  $C_7-C_{18}$  hydrocarbons of linear or branched configuration,  $C_2-C_6$  alkanoyl esters, and triglycerides of  $C_2-C_6$  carboxylic acids.

- 50. (Previously Presented) The method of claim 46, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.
  - 51. (Previously Presented) The method of claim 45, comprising sumatriptan succinate.
  - 52. (Canceled).
- 53. (Previously Presented) The method of claim 45, wherein the amount of the spray is predetermined.

Claims 54-62 (Canceled).

- 63. (Previously Presented) The method of claim 1, further comprising treating migraines in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray.
  - 64. (Canceled).
- 65. (Previously Presented) The method of claim 24, further comprising treating migraines in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray.
  - 66. (Canceled).

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67. (Previously Presented) The method of claim 45, further comprising treating migraines in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray.

68. (Canceled).

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